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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/229,283	01/13/1999	DAVID E. FISCHER	48012	7211

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/229,283	FISCHER, DAVID E.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *19 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1,4,13,14 and 16-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *14 and 23* is/are allowed.

6)☐ Claim(s) *1, 4, 13, 16-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The Amendment filed October 19, 2006 in response to the Office Action of April 19, 2006 is acknowledged and has been entered. Previously pending claim 21 has been amended. Claims 1, 4, 13-14, 16-23 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are being maintained and new grounds of rejection:

Claim Rejections - 35 USC 112

4. Claims 1, 4, 13, 18-20, 22-23 remain rejected and claims 16-17 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed April 19, 2006, Section 5, pages 2-6.

Applicant submits a third Declaration of David E. Fisher in support of the written description of the instantly claimed invention.

A review of the Declaration reveals that the Declarant reiterates and summarizes the first declaration of David E. Fisher. The Declarant states that (1) he discovered that expression of Mi in a malignant cell is indicative of melanoma, (2) a preferred method for determining the expression of Mi was using an antibody that selectively recognizes the expression of Mi, (3) it is unnecessary for antibody to distinguish between the different isoforms of Mi, (4) the skilled artisan knows that an antibody that selectively binds to a protein means an antibody that would not cross-react with a wide range of proteins, (5) the specification exemplifies the production of a single monoclonal antibody against the amino terminal Taq-Sac fragment, monoclonal antibody D5, (6) at the time the invention was made, the skilled artisan knew how to prepare antibodies, (7) homologous regions with related proteins were known, (8) the skilled artisan, based on what Declarant taught would known what was being described, (9) phage display systems can be

used to screen for antibodies with desired properties, (10) antibodies are not defined by an amino acid sequence but rather by their ability to bind to a particular protein, (11) one only needs an antibody that binds Mi and it is not necessary to distinguish between different isoforms of Mi, (12) it is not necessary for the antibody to bind to some specific binding site on the protein because one is not looking to block some activity, only to determine whether or not Mi is present, (13) selection of a desired type and affinity of produced antibodies by screening is part of any method of making antibodies – Declarant points to Hoogenboom for a conventional screening method.

Applicant's arguments incorporate the discussion in the Declaration as follows:

Applicant argues that it is not necessary that antibody distinguishes between the different isoforms of Mi. The argument has considered but appears to be moot since the rejection of record is not drawn to antibodies that distinguish between different isoforms of Mi, but rather is drawn to antibodies that selectively/uniquely bind to Mi.

Applicant argues that the skilled artisan knows that an antibody that selectively binds to a protein means that the antibody would not cross-react with a wide range of proteins and points once again to the single example found in the specification that is to monoclonal antibody D5 that binds to the amino terminal Taq-Sac fragment of human Mi. Applicant reiterates arguments drawn to the preparation of antibodies. The arguments were previously considered but not found persuasive for the reasons of record.

Applicant argues that unlike other types of proteins and certainly nucleic acids, antibodies are not typically defined by an amino acid sequence or a

nucleotide sequence, but rather by their ability to bind to a particular protein. The argument has been considered but has not been found persuasive because the claims are not drawn to any antibody that binds to a particular protein, but rather are drawn to antibodies that bind to Mi that are selective for/unique to Mi and for the reasons of record, the specification as originally filed does not provide a written description for the broadly claimed antibodies.

Applicant argues that screening for antibodies with a desired type and affinity of produced antibodies is routine in the art. The argument has been considered but has not been found persuasive because the claims as currently constituted are not drawn to a method of screening for antibodies that are selective for/unique for Mi binding, but rather are drawn to a method of diagnosing melanoma with antibodies that are selective for/unique to Mi. Applicant is reminded that 35 USC 112, first paragraph requires that the specification teach how to make and use a claimed invention. In the absence of a teaching drawn to unique/selective sites for binding, antibodies selective/unique for Mi, other than the Taq-Sac region or antibody exemplified, the specification does not provide an adequate written description of the claimed invention. For the reasons of record, in the absence of a written description for the broadly claimed invention, the instantly claimed invention does not meet the requirements of the code.

Applicant argues and points to Hoogenboom to show routine methods of screening for antibodies and states that given the conventional nature of the art that the instant specification provides the type of guidance and description necessary. The argument has been considered but has not been found persuasive for the reasons set forth previously and above. Again, Applicant is reminded that 35 USC 112, first paragraph requires that the specification teach how to make and use the

claimed invention. The instant specification does not provide a written description of the claimed invention and therefore does not meet the requirements of the code.

Applicant argues that it is not necessary for an antibody to bind to a specific binding site on the protein because one is not looking to block some activity, but rather, the goal is to identify whether or not Mi is present. The argument has been considered but has not been found persuasive because contrary to Applicant's arguments, the binding of antibody to a specific binding site is absolutely required since the site must be selective for/unique to Mi. The claims are not drawn to any antibody that binds as suggested by Applicant, but rather are drawn to antibodies that selectively/uniquely bind to Mi and for the reasons of record, the specification as originally filed does not provide a written description for the broadly claimed antibodies.

Applicant does not agree with Examiner wherein Examiner sees no nexus between the present invention and Capon v. Eshhar. Applicant argues that the court specifically held that the "written description" requirement does not require that "every invention must be describe the same way" and as explained above, looking at what the invention being claimed is, and the antibody field, it is clear that the specification satisfies the written description requirement. The argument has been considered but is not found persuasive because it is unclear to Examiner exactly what Applicant is trying to indicate. Although Applicant starts the argument by disagreeing with Examiner about the nexus between the present invention and Capon v. Eshhar, Applicant does not refer to Examiner's detailed discussion of the differences in fact patterns between Capon v. Eshhar and the instantly claimed invention found on pages 3-4 of the previous paper. It does appear, however, that Applicant is agreeing with Examiner that the fact patterns

are not the same since Applicant argues that the court specifically held that the "written description" requirement does not require that "every invention must be describe the same way". Further, although Applicant appears to again suggest that screening satisfies the written description requirement, for the reasons set forth previously and above, the specification does not provide an adequate written description of the claimed invention.

Finally, Applicant argues that the sequence of Mi was known and homologous regions with related proteins were known and thus the claimed invention was precisely defined so as to distinguish it from others and such that the skilled artisan knows what is being described. The argument has been considered but has not been found persuasive because the selectivity/uniqueness of binding of the claimed antibodies is not limited to related proteins. Applicant clearly recognizes the phenomenon of cross-reactivity, but neither the specification as originally filed nor the art of record provides guidance on proteins that are not related to Mi, but which also would be bound by antibodies that bind to Mi. The simple statement that the antibody is selective/unique does not provide a written description of the broadly claimed selective/unique sites that are found on Mi or antibodies that will bind specifically, selectively, uniquely to those sites.

Further, Applicant's final argument is contradictory at best. Applicant has argued that one could discover the antibodies that function as claimed by screening methods conventional in the art and then states that since the sequence of Mi was known and homologous regions with related proteins were known at the time the invention was made, that the invention is precisely defined. Thus, it appears that Applicant is aware that there are proteins other than those related to Mi that would be bound by antibodies that were "selective/unique" to Mi compared to related

proteins and that these could only be discovered by screening methods. Thus the broadly claimed invention is not precisely defined so as to distinguish it from others and the skilled artisan would in fact not known what is being described and the specification does not provide a written description of the invention as claimed. For the reasons set forth previously and above, the specification does not provide an adequate written description of the claimed invention.

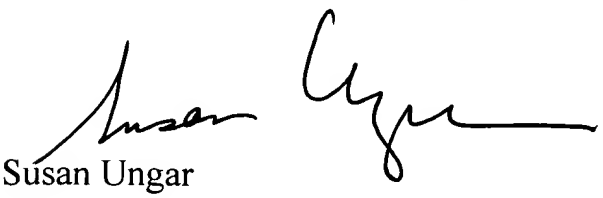
Applicant's Declaration and arguments have been considered but have not been found persuasive and the instant rejection stands.

5. Claims 14 and 21 are allowable.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.



Susan Ungar
Primary Patent Examiner
January 3, 2007